

Notice of Allowability

Application No.

10/749,387

Examiner

Samuel W. Liu

Applicant(s)

FUKUCHI ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/28/05.
2. ☒ The allowed claim(s) is/are 1-3 and 5-11.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 1/24/06.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

The amendment filed 12/28/05, which amends claims 1 and 9, and cancels claims 12-34 has been entered. Pending claims 1-11 are examined in this Office action.

EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Daniel R. Evans on January 24, 2006. Applicants agree to the examiner proposed amendment to claims 1-2, 4, 7 and 9 (see below).

Amendments to the claim:

The pending claims 1-2, 4-5, 7 and 9 have been amended as follows. Please replace the previous claims with the claims shown below.

Claim 1 (*Amended*): A method for producing a protein having an antithrombotic activity, which comprises replacing, in a protein that has the amino acid sequence of SEQ ID NO: 1 and forms a tertiary structure, from N-terminus to C-terminus, composed of a first β strand (β 1), a first α helix (α 1), a second α helix (α 2), a second β strand (β 2), a loop, a third β strand (β 3), a fourth β strand (β 4) and a fifth β strand (β 5) in this order from the amino terminus, at least one amino acid residue in a region from α 2 to β 2 in the protein corresponding to the sequence of the amino acid residues 47 to 72 in SEQ ID NO:1, a region from β 3 to β 4 in the protein corresponding to the sequence of the amino acid residues 94 to 111 in SEQ ID NO:1, or in the regions from α 2 to β 2 and from the region from β 3 to β 4 so that electric charge of the amino acid residue is substituted towards positive direction as compared to the unsubstituted amino acid.

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Claim 2 (*Amended*): The method according to Claim 1, wherein at least one acidic amino acid residue in the region from $\alpha 2$ to $\beta 2$, a the region from $\beta 3$ to $\beta 4$, or in the regions from $\alpha 2$ to $\beta 2$ and the region from $\beta 3$ to $\beta 4$ is replaced with a neutral amino acid residue to change electric charge of the amino acid residue towards positive direction as compared to the unsubstituted amino acid.

Delete claim 4.

Claim 5 (*Amended*): Change “according to claim 4” to “according to claim 1”.

Claim 7 (*Amended*): The method according to claim 1, which further comprises deleting a region containing the loop structure existing between $\beta 2$ and $\beta 3$ in such a manner that the ~~secondary or~~ tertiary structures of $\beta 2$ and $\beta 3$ are maintained, or replacing the region with one or more amino acid residue(s) in a number required to maintain the ~~secondary and~~ tertiary structures of $\beta 2$ and $\beta 3$, said amino acid residue(s) being selected from the group consisting of a glycine residue, an alanine residue, a serine residue and a cysteine residue.

Claim 9 (*Amended*): A method for producing a protein having an antithrombotic activity, which comprises replacing, in a protein that has the amino acid sequence of SEQ ID NO: 1 and forms a tertiary structure, from N-terminus to C-terminus, composed of a first β strand ($\beta 1$), a first ~~a~~ α helix ($\alpha 1$), a second α helix ($\alpha 2$), a second β strand ($\beta 2$), a loop, a third β strand ($\beta 3$), a fourth β strand ($\beta 4$) and a fifth β strand ($\beta 5$) in this order from the amino terminus, at least one amino acid residue in a region from $\alpha 2$ to $\beta 2$ in the protein corresponding to the sequence of the amino acid residues 47 to 72 in SEQ ID NO:1, a region from $\beta 3$ to $\beta 4$ in the protein corresponding to the sequence of the amino acid residues 94 to 111 in SEQ ID NO:1, or in the regions from $\alpha 2$ to $\beta 2$ and from the region from $\beta 3$ to $\beta 4$ so that electric charge of the amino acid residue is substituted towards positive direction as compared to the unsubstituted amino acid, which further comprises covalently bonding a polyoxyalkylpolyol group to the protein.

Amendment to the specification:

On page 14, line 20, “Fig. 5 shows” should be changed to “Fig. 5A-5D show”; line 22, “Fig. 6 shows” to “Fig. 6A-6B show”.

On page 15, line 5, “Fig. 10 shows” should be changed to “Fig. 10A-10B show”.

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On page 2 (amended specification filed 10/2/04), "*This application is a division of U.S. Application Serial No. 09/969.763, filed October 4, 2001*" should be changed to "This application is a division of U.S. Application Serial No. 09/969.763, filed October 4, 2001, now US Patent No. 6,710,031".

Conclusion: claims 1-3 and 5-11 are allowed.

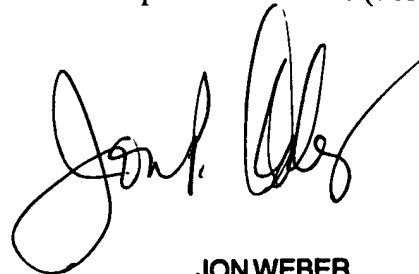
The following is an **Examiner's Statement of Reasons for Allowance**: The applicants' amendment filed 9/8/05 obviates the rejection under 35 USC 112, first paragraph with regard to "an amino acid sequence of SEQ ID NO:1" (claim 1) which reads on and is directed to a fragment thereof, because the amended claim 1 has specified the amino acid sequence of SEQ ID NO:1 which refers unambiguously to the full-length sequence of SEQ ID NO:1. Thus, claims 1-3 and 5-11 are allowable over the art of record.

Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The Examiner can normally be reached from 9:30 A.M. to 6:00 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jon Weber, can be reached at (571) 272-0925. The official fax number for Technology Center 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



Samuel W. Liu, Ph.D.
Art Unit 1653, Examiner
January 24, 2006



JON WEBER
SUPERVISORY PATENT EXAMINER